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June 14, 2018

The Honorable Scott Gottlieb
Commissioner, Food and Drug Administration (FDA)
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted electronically via: https://www.regulations.gov

RE: Docket No. FDA-2017-N-6189, "Tobacco Product Standard for Nicotine Level of Combusted Cigarettes"

Dear Commissioner Gottlieb:

The National Business Group on Health (NBGH or the "Business Group") appreciates the opportunity to comment on FDA's advance notice of proposed rulemaking (ANPRM) to obtain information for consideration in developing a tobacco product standard to set the maximum nicotine level for cigarettes. In particular, the Business Group appreciates providing the agency with employers' perspectives on tobacco in the workplace including associated costs, lost productivity, absenteeism, liability concerns, increased workers' compensation claims, and other direct and indirect impacts. Tobacco use is a major concern for employers. When employees use tobacco, it is costly to the organization and leads to productivity loss, poor employee health status and safety risks. In the U.S., tobacco-free workplaces have become common. Additionally, there is growing interest among multinational corporations to go tobacco-free in their facilities around the world.

The National Business Group on Health represents 421 primarily large employers, including 74 of the Fortune 100, who voluntarily provide group health and other employee benefits to over 55 million American employees, retirees, and their families. While we cannot offer the FDA specific expertise on the appropriate scientific levels of maximum nicotine, or the potential scope of this ANPRM, we concurrently applaud the FDA for taking a close look at this important issue. Tobacco cessation is a top concern for our members and, to the extent that FDA solicits validated and sound scientific data to support an appropriate maximum level of nicotine in combustible cigarettes, we would welcome the opportunity to support an effort that could make cigarettes either less- or non-addictive.

Below, we expand upon the Business Group's perspectives on the impact of employee tobacco usage to large employers.

Overview: Workplace Costs of Tobacco Use[i, ii, iii]

Employer Direct Costs	Employer Indirect Costs
• Greater health insurance costs and claims • Greater life insurance premium costs and increased claims • Greater potential disability costs • Greater potential workers' compensation payments and occupational health events	• Recruitment and retraining costs resulting from loss of employees to tobacco-related death and disability • Lost productivity • Greater amount of work time used on tobacco-use habits and routines • Greater number of disciplinary actions • Smoke pollution (increased cleaning and maintenance costs) • Air cooling, heating and ventilation costs • Accidents and fires (plus related insurance costs) • Property damage (plus related insurance costs) • Greater risk of industrial or occupational injuries • Liability and litigation costs associated with exposure to environmental tobacco smoke • Illness and discomfort among nonsmokers exposed to secondhand smoke

Increased Health Care Utilization and Costs due to Tobacco Use

- It is estimated that approximately 8% of healthcare costs can be attributed to smoking.[iv]
- In two studies, the average healthcare costs for employees who use tobacco were $371-$587 higher per year compared to non-tobacco users[v, vi] – Employees who smoked had higher rates of emergency room visits (393 vs. 249 per 1000); inpatient admissions (50.8 vs 38.7 per 1000); and medication refills per year (9.9 versus 8.8).[vii]
- When medical, absenteeism, presenteeism, short-term disability and workers' compensation costs are combined, smokers cost between $900 to $1383 per year more than non-smokers; an increase of 10%-16%.[viii]

Lost Productivity Due to Tobacco Smoke

- A national study based on American Productivity Audit data of the U.S. workforce found that tobacco use was one of the greatest causes of lost worker production time (LPT). Additionally, LPT increased in relation to the amount smoked. LPT estimates for workers who reported smoking one pack of cigarettes per day or more was 75% higher than that observed for nonsmoking employees or employees who had previously quit smoking.[ix]
- Across four U.S. studies, smokers had 2.0-2.9 additional sick days annually compared to nonsmokers.[x, xi, xii, xiii]
- Across three U.S. studies, smokers had a 1.9%-4% reduction in productivity due to presenteeism.[xiv, xv, xvi]
- Lost productivity due to smoke breaks can be significant, but a challenge to quantify. Research suggests smokers smoke on average 5 cigarettes per day, but only 2 outside of sanctioned breaks.

The length of breaks can vary based on company policies and locations in which smoking is permitted. Research suggests it can be as little as 6 minutes or as high as 15-20 minutes.[xvii, xviii]

Legal Liabilities of Secondhand Smoke

- Nonsmoking employees can receive workers' compensation, unemployment compensation, disability benefits, and other settlements based upon their exposure to secondhand smoke in the workplace.[xix]
    - Worker's Compensation: An employee can file a claim for an injury or illness from secondhand smoke.
    - Disability Discrimination: An employee can file a claim if he or she has a disability that becomes worse or is complicated by secondhand smoke.
    - Common Law Duty: An employee can file a claim that the employer has not provided a safe work environment; under common law duty, employers are responsible for creating a workplace that is safe for employees.

Employers Promote Tobacco Cessation Through Incentives and Surcharges

Being mostly self-funded, our employer members as well as many other employers, have a vested interest in more effective, efficient health care. To that end, and given the impact of employee tobacco use to our members, they have been actively engaged in implementing methods to discourage employees from using tobacco, or encourage them to quit. Depending on the employer, tobacco-related incentives have been offered in one of several ways:

- As an incentive for tobacco users' participation in a tobacco cessation program;
- As a premium surcharge or discount that applies to the entire population;
- As part of an outcome-based incentive design in which tobacco use is one outcome; or
- As a gateway to additional incentives or a preferred health plan.

The designs and values of tobacco-related incentives vary tremendously across employers. Based on 15 member companies profiled in the Business Group's Financial Incentives: Corporate Examples and Outcomes chart, tobacco-related incentives range from $130 to $1,300 annually. However, this variation is highly dependent on the design. Incentives for participation in a tobacco cessation program or as a standalone tobacco surcharge or discount tend to be much higher than those in which tobacco is included as an "outcome" in outcome-based designs.

Based on survey data:

- Sixty-eight percent of employers offer some form of an incentive for participation in tobacco cessation programs, 10% of whom design it as a penalty for nonparticipation. The average incentive was $331.[xx]
- Thirteen percent of employers offer a premium discount for non-tobacco users while 28% position the incentive as a premium surcharge for tobacco users. The average incentive was between $395 and $442 depending on how it was offered.[xxi]
- Among employers who include tobacco status as part of a specific outcomes- based incentive program, the average amount was $199 in 2016.[xxii]

A small portion of employers are withdrawing the financial value tied to tobacco use and instead positioning non-tobacco use as a gateway to other incentives or preferred health plans. Based on 103 employer responses in the 2015 National Business Group on Health/Fidelity Investments Survey, 10% of employers positioned non-tobacco use as a gateway to additional incentives and 1% limited eligibility to specific health plans based on tobacco-use status.[xxiii]

Research on Tobacco-Related Incentives

While the designs across employers vary, the research on tobacco-related incentives is focused mostly on incentives for participation in tobacco cessation programs. This research shows that incentives tied to completion of the program and smoking cessation may prove effective; however, regulations must be considered when tying any incentive to a health outcome such as tobacco cessation, and a reasonable alternative must be provided.

- A 2006 study that offered smokers $20 per class attended and $100 for smoking cessation found that incentives significantly increased participation and smoking cessation rates. The incentive group had higher enrollment compared to the group that did not receive incentives (43% versus 20%), as well as higher completion rates (26% versus 12%) and short-term quit rates (16.3% versus 4.6%).[xxiv]
- A 2009 study offered smokers $100 for the completion of a smoking cessation program, $250 for cessation within six months and an additional $400 for remaining smoke-free six months after cessation. Six months after the program began, the incentive group had participation and quit rates of 15.4% and 20.9%, respectively, versus 5.4% and 11.8% for the control group. Confirmed quit rates at 9 and 12 months were three times greater in the incentive group (14.7% versus 5%). Although cessation rates decreased over time, after 18 months, 9.4% of the incentive group remained smoke-free as compared to only 3.6% of the control group.[xxv]
- A 2015 study of CVS Health employees compared two different types of incentive designs on tobacco program participation and cessation. Employees assigned to the reward-only group received $800 after being tobacco free for 6 months. A second group of employees were asked to participate in a deposit contract where they deposited $150 of their own money at the beginning of the program. If successful in quitting and remaining tobacco free for six months, these employees would be refunded their $150 and receive an additional $650. The results showed that the deposit contract resulted in greater cessation, but was less effective across the population due to low participation.[xxvi]

Thank you for considering our comments and recommendations regarding tobacco cessation interventions. We look forward to reading the comments to the docket and following the FDA's progress on this issue. Please contact me or Steven Wojcik, the National Business Group on Health's Vice President of Public Policy, at (202) 558-3012 if you would like to discuss our comments in more detail.

Sincerely,

Brian Marcotte
President and CEO

[i] Smoke-free work sites top ten financial benefits to employers. Western CAPT/CASAT. University of Nevada, Reno.
[ii] Center for Health Promotion Publications. The Dollar (and sense) Benefits of Having a Smoke-Free Workplace. Lansing, Michigan Tobacco Control Program; 2000. This presentation is for National Business Group on Health® members only. It should not be reproduced or quoted without permission from National Business Group on Health® This presentation is for National Business Group on Health® members only. It should not be reproduced or quoted without permission from National Business Group on Health® Sources
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